United States District Court, Northern District of Illinois

							
Na	me of Assigned Judge or Maglstrate Judge	Jailles	B. Zagel	Sitting Judge if Other than Assigned Judge			
C/	ASE NUMBER	02 (C 4782	DATE	7/26	5/2004	
CASE TITLE			CYTOMEDIX, INC. vs. LITTLE ROCK FOOT CLINIC				
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(2)	☐ Brief	Brief in support of motion due					
(3)	☐ Answ	Answer brief to motion due Reply to answer brief due					
(4)	□ Rulin	Ruling/Hearing on set for at					
(5)	☐ Status	Status hearing[held/continued to] [set for/re-set for] on set for at					
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(9)	☐ This o	case is dismissed [with CP4(m)	h/without] prejudic Rule 41.1 □ FRC	e and without costs[by/s P41(a)(1)	agreement/pursuant to] 1(a)(2).		
(10)	[Other docket entry] Motion (52-1) for leave to file brief under seal is granted. Motion (54-1) to strike is denied. Motion (60-1) for summary judgment is granted. Enter Memorandum Opinion and Order.						
(11) [For further detail see order attached to the original minute order.]							
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UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

CYTOMEDIX, INC.,

Plaintiff,

v.

LITTLE ROCK FOOT CLINIC, P.A., MARVIN F. COHEN, R. ALEX DELLINGER, and CALVIN P. BRITTON, III,

Defendants.

DOCKETED AUG 0 4 2004

No. 02 C 4782 Judge James B. Zagel

MEMORANDUM OPINION AND ORDER

Plaintiff Cytomedix has moved for summary judgment of infringement of United States Patent No. 5,165,938 ("the '938 patent"), which claims processes for facilitating healing of damaged tissue and/or wounds using materials released by platelets during a platelet release reaction. Defendants Little Rock Foot Clinic, P.A., Marvin F. Cohen, R. Alex Dellinger, and Calvin P. Britton, III ("the Defendants") are accused of infringement for their use of a system for treating chronic non-healing wounds provided by third-party SafeBlood Technologies, Inc. ("SafeBlood"). On March 23, 2004, I issued a ruling construing the disputed claim terms of the '938 patent. Cytomedix now argues that under the adopted claim construction, there is no genuine issue of material fact as to whether the SafeBlood process, and the Defendants' use of it, literally infringes the '938 patent. Cytomedix therefore asserts that it is entitled to summary judgment that construed claims 1-2, 4-8, and 10-12 are infringed by Defendants.



Legal Standards Governing Summary Judgment of Infringement

Infringement requires that every limitation of a claim be met in the accused structure or process either literally or under the doctrine of equivalents. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997). A claim is literally infringed when every claim limitation is found in the accused device or process, i.e., when the properly construed claim reads on the accused device or process exactly. Amhil Enters. v. Wawa, Inc., 81 F.3d 1554, 1562 (Fed. Cir. 1996). The doctrine of equivalents provides a basis for finding infringement when a product or process does not literally infringe upon the express terms of a patent claim but "there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson, 520 U.S. at 21. Cytomedix has only argued, however, that the '938 patent has been literally infringed.

In order to conclude that the '938 patent is infringed, I must first determine the meaning and scope of the claims, and then compare the properly construed claims to the accused device or process. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Claim construction is a matter of law, Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc), but a determination of infringement is a question of fact, Instituform Techs. v. Cat Contr., Inc., 161 F.3d 688, 692 (Fed. Cir. 1998). I have already completed the first step of this process by construing the disputed claim terms. See Cytomedix, Inc., v. Little Rock Foot Clinic, P.A., No. 02 C 4782, 2004 WL 609330 (N.D. Ill. Mar. 24, 2004). In considering this motion for summary judgment, I take the second step and compare the properly construed claims to the accused device or process. I approach this motion for summary judgment on the fact issue of infringement with great care. Palumbo v. Don-Joy

Co., 762 F.2d 969, 974 (Fed. Cir. 1985), overruled on other grounds by Markman, 52 F.3d at 976-979.

Summary judgment of infringement will be appropriate if, in comparing the construed claims to the accused process, I find that there is no genuine issue of material fact and no expert testimony required to explain the nature of the patented invention or the accused process, or to assist in their comparison. See Amhil, 81 F.3d at 1557-58. Summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). I will draw all reasonable factual inferences in favor of the Defendants. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). At the same time, the burden is on Cytomedix to show that the record does not disclose a genuine dispute of a material fact. See Haefling v. UPS, 169 F.3d 494, 497 (7th Cir. 1999). If Cytomedix meets this burden, then the Defendants will have to set forth specific facts showing that there is a genuine issue for trial. See Celotex, 477 U.S. at 324.

The '938 Patent and the Accused SafeBlood Graft System

The claim terms whose meanings were in dispute and construed by my Order of March 23, 2004 are independent claims 1 and 12 of the '938 patent, which read as follows, with the disputed terms emphasized:

- 1. A process for treating damaged, live, animal tissue which comprises applying over the damaged tissue an effective amount of a treating composition containing the materials released by platelets during the platelet release reaction and facilitating healing of the damaged tissue.
- 12. A process for treating a wound of a live animal which comprises applying over the wound an effective amount of a treating composition containing the materials released by platelets during the platelet release reaction and facilitating healing of the wound.

I construed the term "effective amount" to mean "a sufficient amount of treating composition to facilitate healing." The term "treating composition containing the materials released by platelets during the platelet release reaction" was construed to mean "a composition that has all of the various components released by platelets during the platelet release reaction and may have other components." Cytomedix, 2004 WL 609330 at **2, 5. The language of the claim, the patent specification, and the prosecution history all support these constructions. A significant amount of the claim construction dispute was over the extent to which the claims were limited to compositions free of platelet ghosts or other materials. I found that the claims were not restricted to protecting compositions including only those various materials. Id. at **5-9. The construction makes this clear by including the phrase "... and may have other components." I also found that the claimed treating composition must include all of the various components released during the platelet release reaction.

Cytomedix alleges that the Defendants have infringed the '938 patent by using the SafeBlood Graft System. Because the Defendants admit they have used and continue to use the SafeBlood process, the dispositive question in determining whether Cytomedix is entitled to summary judgment of infringement is, therefore, whether the SafeBlood process literally

infringes on the '938 patent.¹ If every claim limitation of the '938 patent is found in the SafeBlood process, then it literally infringes the patent. See Amhil, 81 F.3d at 1562.

The Defendants argue that the SafeBlood process does not infringe the '938 patent for various reasons. First, Defendants note that scientific literature shows that the type and quantity of chemical activator being used to trigger the platelet release reaction may result in different varieties of releasates or combinations of releasates. Defendants claim that whereas the '938 patent requires all contents of the platelets to immediately flush, purge, or be released, the SafeBlood process may only partially activate the platelets because the chemical agonists used may be different or in different amounts. Accordingly, Defendants claim that there is a factual question as to whether the SafeBlood process actually contains all materials released by platelets in the platelet release reaction, as is required under the '938 patent. In a related argument, Defendants also claim that summary judgment is inappropriate because the SafeBlood Graft system uses less thrombin than the 5000 units/mL used in Cytomedix's Autologel. Finally, along the same line of analysis, Defendants argue that there is evidence that Cytomedix's own process, Autologel, does not produce a treating composition that contains "all" the materials

¹ The Defendants argue in their brief that there is a genuine issue of fact because they used other autologous cellular processes and platelet products in addition to the SafeBlood Graft system. Whether there is an issue of fact regarding what, if any, additional processes the Defendants use is, however, irrelevant. The only process used by the Defendants that is at issue in this suit and summary judgment motion is the SafeBlood Graft. Much of the Defendants' brief is spent attempting to raise issues of fact that are not material to the motion for summary judgment of infringement of the '938 patent.

² Thrombin is the primary agonist, or activator, used in the platelet release reactions at issue.

released by platelets because it lacks one major component of platelets known to be released under certain conditions.³

In the end, all of these arguments are irrelevant because they are all premised on a fundamental misunderstanding of the claim construction contained in my Order. The Defendants would like the '938 patent to be limited to protecting treating compositions that contain *all* components that *are known to be released* by platelets during platelet release reactions. Instead, the claims were construed to mean that the '938 patent protects a treating composition containing all of the various components [actually] released by platelets during the platelet release reaction. This does not require the "complete release of all materials known to be released by platelets," as the Defendants repeatedly argue. Nor does the construction mean that there must be a minimum release of materials from the platelets, or a complete activation of platelets, in order for the treating composition to be covered by the '938 patent. My Order construing the disputed claims makes sufficiently clear that complete activation of the platelets is not required by the patent. Accordingly, Defendants' arguments – even if true – are irrelevant for the purpose of summary judgment here.

Moreover, the fact that Cytomedix's Autologel uses a particular amount of thrombin to cause the platelet release reaction, and may therefore contain a different variety of released components, is beside the point, because the '938 patent protects treating compositions that contain whatever components are released during platelet release reactions and from which no

³ The Defendants also claim that Cytomedix must differentiate among patients who were treated with the SafeBlood process and those who were treated with a different healing method. They also urged me to understand the doctors as researchers. Neither of these points dispute the central allegation being considered in this motion for summary judgment of infringement, that the Defendants have used and use a process (SafeBlood Graft) that infringes on the '938 patent.

components have been removed or isolated before application to the wound. The construed patent claims are broad enough to cover such compositions containing a different variety of released components, or components released from platelets activated by a different amount (or type) of agonist, as long as the compositions contain *all* of the components that were released during the particular platelet release reaction. The Defendants' comparison of the amount of thrombin used in the SafeBlood Graft system with the amount used in Cytomedix's Autologel is also irrelevant because Autologel is Cytomedix's preferred way of implementing the process protected by the '938 patent, it does not constitute a definitive or exhaustive definition of the patent's claims.

In the end, if the Defendants cannot show that the SafeBlood Graft system does not involve the application of an effective amount of a treating composition containing all of the various components released by platelets during the platelet release reaction, then there is no genuine issue of material fact to preclude summary judgment. Cytomedix has shown, and the Defendants have either admitted or not disputed, that the SafeBlood system, as described and performed by the Defendants, involves centrifuging the patient's blood to separate out the platelet rich plasma ("PRP") and — without isolating individual factors from the materials released by the platelets or centrifuging the PRP further — mixing the PRP with thrombin, calcium chloride, and collagen. The resulting mixture is applied about one minute later to the wound, again without any of the released components being removed. The size of the wound and the doctor's experience generally determines the amount of composition applied, which is an amount sufficient to fill the wound. This amount meets the definition of an "effective amount," which is "a sufficient amount of treating composition to facilitate healing." See Cytomedix, No.

02 C 4782, 2004 WL 609330 at *3. This evidence demonstrates that the treating composition used by the Defendants in the SafeBlood Graft system contains "all of the various components released by platelets during the platelet release reaction" caused by the SafeBlood Graft's use of thrombin, calcium chloride, and collagen as agonists, because no components of the PRP releasate are removed or isolated prior to application on the wound.⁴

Cytomedix established through affidavits and depositions the undisputed and admitted facts in this case and demonstrated that they are sufficient to find literal infringement of the '938 patent's claims. The Defendants failed to show that there remains a genuine issue of material fact for trial as to independent claims 1 and 12. Their reliance on a misreading and misinterpretation of the construction of these disputed claims resulted in their failure to address meaningfully the dispositive issues I had to consider in deciding this motion for summary judgment. Every limitation of the '938 patent is found in the SafeBlood Graft system when compared to the construed claims. See Markman, 52 F.3d at 976. Expert testimony is not necessary to determine whether or not all of the components released from platelets during the platelet release reaction are contained in the SafeBlood system's treating composition. See Amhil, 81 F.3d at 1557-58. Established facts show that the Defendants do not remove or isolate any of the released components, nor does the SafeBlood process call for it, so that all of the various released components are contained in the treating compositions used by the Defendants. I therefore find that the Defendants infringed independent claims 1 and 12 of the '938 patent and, as a result, dependent claims 2, 4-8, and 10-11, for which there are no independent issues of

⁴ SafeBlood's training manual describes an identical process to that used by Defendants (as they described it in deposition testimony), and Defendants have not disputed that they used the SafeBlood Graft system as described in the manual.

material fact. Because there is no genuine issue of material fact, I grant summary judgment in favor of Cytomedix.⁵

For the reasons stated above, Cytomedix's Motion For Summary Judgment of Infringement is GRANTED, but its Motion to Strike Paragraphs 5, 6, 8, 9 and 10 of the Affidavit of Mark Murphey Henry and Related Exhibits C, D, F, G and H is DENIED.

ENTER:

James B. Zagel

United States District Judge

DATE: 26 July 2003

⁵ Because I grant summary judgment in favor of Cytomedix, its Motion to Strike is moot.